

## CLAIMS

What is claimed is:

- 5           1.       A system for the creation or modification of an orthopedic joint within a mammalian body by the placement of an interpositional implant, the system comprising one or more apparatuses for: a) preparing the joint to receive the implant, b) determining an appropriate implant size for a particular joint, c) determining an appropriate implant thickness, d) inserting the implant into the joint, and/or e)
- 10       securing the implant within the joint to a desired extent.
2.       A system according to claim 1, wherein the joint preparation apparatus comprises a smoothing device for preparing one or more surfaces within an articulating joint site, the device comprising a substantially flat, straight or curved, blade having a proximal portion adapted to be hand held and/or attached to a powered
- 15       surgical instrument, and a distal portion having at least one major surface provided with a texture adapted to smooth cartilage within the joint site.
3.       A system according to claim 2 wherein the blade is fabricated from surgical stainless steel, and a distal portion of the blade is textured by providing either a plurality of closely spaced holes extending through the width of the blade or a
- 20       plurality of pegs or ridges positioned upon the blade.
4.       A system according to claim 1 wherein the joint sizing apparatus comprises a device adapted for use in the knee in order to determine a dimension between the anterior and posterior edges of the tibial surface, while also providing a suitable depth measurement of the tibial depression at a point approximately midway
- 25       between the raised anterior and posterior edges of the tibial plateau.
5.       A system according to claim 4 wherein the joint sizing apparatus comprises a caliper adapted for measuring one or more dimensions associated with the knee, including to measure one or more dimensions selected from the group consisting of an anterior-posterior dimension, a medial-lateral dimension, and a
- 30       height/depth dimension.

6. A system according to claim 1 wherein the apparatus for determining joint thickness comprises a plurality of trial implants of one or more varying dimensions and/or configurations.

7. A system according to claim 6 wherein the the plurality of trial  
5 implants comprises a plurality of knee implants of varying thickness to account for the ligament laxity in a particular knee joint and incorporate a design feature selected from the group consisting of number coded, bar coded, shape coded, tactile coded and/or visually coded.

8. A system according to claim 1 wherein the apparatus for inserting the  
10 implant comprises a plurality of opposing jaws, together with a handle and a locking mechanism adapted to secure the jaws in position upon an implant.

9. A system according to claim 1 further comprising one or more ancillary components adapted to secure an implant in the body.

10. A system according to claim 1 wherein:  
15 a) the joint preparation apparatus comprises a smoothing device for preparing one or more surfaces within an articulating joint site, the device comprising a substantially flat, straight or curved, blade having a proximal portion adapted to be hand held and/or attached to a powered surgical instrument, and a distal portion having at least one major surface provided with a texture adapted to smooth cartilage  
20 within the joint site,

b) the joint sizing apparatus comprises a device adapted for use in the knee in order to determine a dimension between the anterior and posterior edges of the tibial surface, while also providing a suitable depth measurement of the tibial depression at a point approximately midway between the raised anterior and posterior  
25 edges of the tibial plateau,

c) the apparatus for determining joint thickness comprises a plurality of trial implants of one or more varying dimensions and/or configurations,

d) the apparatus for inserting the implant comprises a plurality of opposing jaws, together with a handle and a locking mechanism adapted to secure the  
30 jaws in position upon an implant,

e) one or more ancillary components are integrated into, and partially extending from, the implant to provide fixation, and

f) one or more interpositional implants wherein at least one implant comprises a partially or fully preformed metallic and/or polymeric components, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in apposition to opposing bone.

11. A joint preparation apparatus adapted for use in the system of claim 1, comprising a smoothing device for preparing one or more surfaces within an articulating joint site, the device comprising a substantially flat, straight or curved, blade having a proximal portion adapted to be hand held and/or attached to a powered surgical instrument, and a distal portion having at least one major surface provided with a texture adapted to smooth cartilage within the joint site.

12. An apparatus according to claim 11 wherein the device is adapted for use with one or more surfaces of the bones in the knee joint.

13. An apparatus according to claim 12 wherein the device is adapted for use in smoothing the condylar surface.

14. An apparatus according to claim 11 wherein the blade is fabricated from surgical stainless steel.

15. An apparatus according to claim 14 wherein a distal portion of the blade is textured by providing either a plurality of closely spaced holes extending through the width of the blade or a plurality of pegs or ridges positioned upon the blade.

16. An apparatus according to claim 15 wherein the device is adapted for use in a reciprocating saw instrument, and fabricated to retain a predetermined curved shape.

17. An apparatus according to claim 16, wherein the device has an overall length of between about 100 mm and 150 mm, with a substantially distal portion having a length of between about 20 mm and about 40 mm.

18. An apparatus according to claim 17 wherein the blade width is between about 5 mm and about 10 mm, and has a thickness of between about 0.3 mm and about 5 mm.

19. An apparatus according to claim 18 wherein the proximal portion of the device is provided in the form of generally circular shaft, adapted to be fixably and releasably positioned within a powered surgical instrument.

20. An apparatus according to claim 9 wherein the powered surgical  
5 instrument is adapted to operate the blade at an excursion distance of between about 0.5 mm and about 10 mm.

21. A joint sizing apparatus for sizing a joint for use in the system of claim 1, adapted for measuring one or more dimensions associated with the knee.

22. An apparatus according to claim 21, wherein the device is adapted to  
10 measure one or more dimensions selected from the group consisting of an anterior-posterior dimension, a medial-lateral dimension, and a height/depth dimension.

23. An apparatus according to claim 22 wherein the device is adapted for use in the knee and can be used to determine a dimension between the anterior and posterior edges of the tibial surface, while also providing a suitable depth  
15 measurement of the tibial depression at a point approximately midway between the raised anterior and posterior edges of the tibial plateau.

24. An apparatus according to claim 21 wherein the apparatus comprises a caliper.

25. An apparatus according to claim 24 wherein the caliper comprises a  
20 handle assembly and a gauge portion adapted to engage the posterior edge of the tibial plateau and without interference from the femoral condyle.

26. An apparatus according to claim 25 further comprising a slide having a raised contact end portion which translates back and forth relative to a rule that can be positioned against the anterior portion of the tibia.

25 27. An apparatus according to claim 26 further comprising a probe positioned along the length of the rule, and optionally movable laterally thereto, in order to measure the depth of any indentation, or bowl shape that the tibial surface may have.

28. An apparatus according to claim 27 wherein the probe is mounted on a  
30 slide, moveable longitudinally with the axis of the rule, to permit it to be adjusted to make depth measurements in various locations.

29. An apparatus according to claim 28 wherein the anterior-posterior dimension of the tibial surface can be read from the rule as the distance between the point contacting the posterior tibial surface edge and a point contacting the anterior edge.

5 30. An apparatus according to claim 21 comprising a caliper adapted for measuring one or more dimensions associated with the knee, including to measure one or more dimensions selected from the group consisting of an anterior-posterior dimension, a medial-lateral dimension, and a height/depth dimension.

10 31. An apparatus for determining joint thickness for use in the system of claim 1.

32. An apparatus according to claim 31, comprising a plurality of trial implants of one or more varying dimensions and/or configurations.

15 33. An apparatus according to claim 32 wherein the plurality of trial implants comprises a plurality of knee implants of varying thickness to account for the ligament laxity in a particular knee joint.

34. An apparatus according to claim 32 wherein the respective trial implants are designed in a manner that eases their selection and use, while serving to minimize error.

20 35. An apparatus according to claim 34 wherein the components are designed in a manner selected from the group consisting of number coded, bar coded, shape coded, tactile coded and/or visually coded.

36. An apparatus for inserting an interpositional arthroplasty implant for use in the system of claim 1.

25 37. An apparatus according to claim 36 wherein the apparatus is adapted to firmly hold an interpositional knee implant.

38. An apparatus according to claim 37 wherein the apparatus comprises a plurality of opposing jaws.

30 39. An apparatus according to claim 38 wherein the apparatus further comprises a handle and a locking mechanism adapted to secure the jaws in position upon an implant.

40. An apparatus according to claim 39 wherein the first and second jaws are pivotally coupled to the handle.

41. An apparatus according to claim 40 further comprising a portion adapted to bias the handle in an open position.

42. An apparatus according to claim 36 wherein the apparatus is adapted to hold an anterior portion of an implant while a posterior portion of the implant is  
5 inserted between a medial condyle of a femur and tibial plateau of a tibia.

43. One or more ancillary components adapted to secure an implant in the system of claim 1.

44. Components according to claim 43 wherein at least one ancillary component is integrated into, and partially extending from, the implant to provide  
10 anterior fixation.

45. A system according to claim 44 wherein the ancillary component comprises one or more protrusions adapted to be attached to either soft tissue and/or bone at the joint site to improve fixation.

46. A system according to claim 45 wherein the protrusions are selected  
15 from the group consisting of sutures and/or fibrous biomaterials integrally formed with the preformed component itself, and one or more separate components for securing the implant to the joint site, selected from the group consisting of adhesives, sutures, pins, staples, screws, and combinations thereof.

47. A system according to claim 1, further comprising one or more  
20 interpositional implants.

48. A system according to claim 47 wherein at least one implant comprises a partially or fully preformed metallic and/or polymeric components, adapted to be inserted and positioned at a joint site to provide an implant having at least one major surface in apposition to supporting bone, and at least a second major surface in  
25 apposition to opposing bone.

49. A system according to claim 48 wherein the implant comprises a knee implant.

50. A system according to claim 49 wherein the implant provides a femoral glide path and convexity of the tibial surface of the implant, together with a  
30 posterior mesial lip.

51. A system according to claim 50 wherein the polymeric components are provided in the form of a single preformed component comprising a biomaterial partially or completely cured in an *ex vivo* mold.

52. A system according to claim 51 wherein the implant comprises tibial  
5 projection(s) adapted to catch the posterior portion of the tibial plateau by extending over the rim of the tibial plateau distally.

53. A system according to claim 52 wherein the preformed component has dimensions on the order of between about 30 to about 60 mm in the anterior-posterior dimension, between about 20 mm to about 40 mm in the medial-lateral dimension,  
10 and a maximum thickness, at the posterior lip, of between about 8 mm and about 20 mm, or about 3mm to about 10 mm greater than the thickness of the implant at the center.

54. A system according to claim 51 wherein the implant further comprises at least one ancillary component integrated into, and partially extending from, the  
15 implant to provide anterior fixation.